

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office			Attorney Docket Number 9233-63		Serial No. 09/873,797		
LIST OF DOCUMENTS CITED BY APPLICANT <i>(use several sheets if necessary)</i>			Applicants: Ekwuribe et al.				
			Filing Date June 4, 2001		Group 1651		
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
1.	GB 1 492 997	11/23/77	Great Britain				
2.	EP 0 031 567	07/08/81	EPO				
3.	JP 1 254 699	10/11/89	Japan				
4.	0511903	04/23/92	EP				
5.	0483465B1	05/06/92	EPO				
6.	WO93/01802	02/04/93	PCT				
7.	WO95/09831	04/13/95	PCT				
8.	EP 0 483 465	08/02/95	EP				
9.	WO95/30641	11/16/95	PCT				
10.	EP 0 597 007	10/16/96	EP				
11.	EP 0 621 777	11/09/96	EP				
12.	EP0797615B1	01/10/97	EPO				
13.	WO98/07745	02/26/98	PCT				
14.	WO99/32134	07/01/99	PCT				
15.	WO99/65941	12/23/99	PCT				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
16.	Abuchowski, A. and F. F. Davis "Soluble Polymer-Enzyme Adducts" pp. 367-383, <i>Enzymes as Drugs</i> , Ed. S. Holcnenberg, John Wiley (1981)						
17.	Agarwal et al. "Polymethacrylate-based Microparticulates of Insulin for Oral Delivery: Preparation and In Vitro Dissolution Stability in the Presence of Enzyme Inhibitors" <i>International Journal of Pharmaceutics</i> 225:31-39 (2001)						
18.	Akiyama et al. "The Synthesis of New Derivatives of 1- β -D-Arabinofuranosylcytosine" <i>Chem. Pharm. Bull.</i> 26(3):981-984 (1978)						
19.	Allaudeen et al. "Orally Active Insulin: A Single Insulin Conjugate Selected for Future Studies" 60th Annual Meeting of the American Diabetes Assoc., Atlanta, GA, June 2000 (Abstract)						
20.	Anderson et al. "HIM2, a Novel Modified Insulin, has Improved Systemic Pharmacokinetics in Normal Dogs, Compared to Unmodified Insulin" American Diabetes Association 62nd Annual Meeting, June 2002 (Abstract)						

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*EXAMINER*Jeffrey E. Russell*

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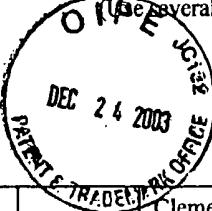
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		Applicants: Ekwuribe et al.	
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40.	Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 25, 2001) (Poster)		
41.	Conradi et al. "The Influence of Peptide Structure on Transport Across Caco-2 Cells" <i>Pharm. Res.</i> 8(12):1453-1459 (1991) ••		
42.	Coombes et al. "Biodegradable Polymeric Microparticles for Drug Delivery and Vaccine Formulation: the Surface Attachment of Hydrophilic Species Using the Concept of Poly(Ethylene Glycol) Anchoring Segments" <i>Biomaterials</i> 18:1153-1161 (1997) ••		
43.	Damge et al. "Poly(alkyl cyanoacrylate) Nanospheres for Oral Administration of Insulin" <i>Journal of Pharmaceutical Sciences</i> 86(12):1403-1409 (Dec. 1997) ••		
44.	Dandona et al. "Effect of an Oral Modified Insulin on Blood Glucose Levels in Fasting and Fed Type 1 Diabetic Patients Receiving a 'Basal' Regimen of Injected Insulin" American Diabetes Association Annual Meeting (June 25, 2001) (Abstract) ••		
45.	Delgado et al. "The Uses and Properties of PEG-Linked Proteins" <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 9(3.4):249-304 (1992)		
46.	Ekwuribe et al. <i>Calcitonin Drug-Oligomer Conjugates, and Uses Thereof</i> , U.S. Serial No. 10/166,355, filed 11/08/2002, including Preliminary Amendment dated 02/26/2003 and Supplemental Preliminary Amendment dated 03/31/2003 ••		
47.	Ekwuribe et al. <i>Mixtures of Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same</i> , U.S. Serial No. 09/873,797, filed 06/04/2001 ••		
48.	Ekwuribe, Nnochiri "Conjugation-Stabilized Polypeptide Compositions, Therapeutic Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" <i>Biotechnology Advances</i> 14(4):575-576 (1996) (Abstract) ••		
49.	Engel et al. "Insulin: Intestinal Absorption as Water-in-Oil-in-Water Emulsions" <i>Nature</i> 219:856-857 (1968) ••		
50.	Fasano, Alessio "Innovative strategies for the oral delivery of drugs and peptides" <i>TIBTECH</i> 16:152-157 (1998) ••		
51.	Forst et al. "New Aspects on Biological Activity of C-peptide in IDDM Patients" <i>Exp. Clin. Endocrinol. Diabetes</i> 106:270-276 (1998) ••		
52.	Gish et al. "Nucleic Acids. 11. Synthesis of 5'-Esters of 1- β -D-Arabinofuranosylcytosine Possessing Antileukemic and Immunosuppressive Activity" <i>J. Med. Chem.</i> 14(12):1159-1162 (1971)		
53.	Gombotz & Pettit "Biodegradable Polymers for Protein and Peptide Drug Delivery" <i>Bioconjugate Chem.</i> 6:332-351 (1995) ••		
54.	Hashimoto et al. "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities" <i>Pharmaceutical Research</i> 6(2):171-176 (1989) •• ••		
55.	Hinds et al. "Synthesis and Characterization of Poly(ethylene glycol)-Insulin Conjugates" <i>Bioconjugate Chem.</i> 11:195-201 (2000) •• Simplex		
56.	Hong et al. "Nucleoside Conjugates. 7. Synthesis and Antitumor Activity of 1- β -D-Arabinofuranosylcytosine Conjugates of Ether Lipids" <i>J. Med. Chem.</i> 29:2038-2044 (1986) ••		
57.	Hostettler et al. "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides" <i>The Journal of Biological Chemistry</i> 265(11):6112-6117 (1990) ••		

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	59.	Kemmler et al. "On the Nature and Subcellular Localization of the Proinsulin Converting Enzymes" <i>Federation Proceedings</i> 30(Abstract 924):1210Abs (1971) /	
	60.	Kemmler et al. "Studies on the Conversion of Proinsulin to Insulin: I. Conversion in Vitro with Trypsin and Carboxypeptidase B" <i>The Journal of Biological Chemistry</i> 246(22):6786-6791 (1971) /	
	61.	King et al. "Preparation of Protein Conjugates with Alkoxyethylene Glycols" <i>Int. J. Peptide Protein Res.</i> 16:147-155 (1980) /	
	62.	Kipnes et al. "Control of Postprandial Plasma Glucose by an Oral Insulin Product (HIM2) in Patients with Type 2 Diabetes" <i>Emerging Treatments and Technologies</i> 26:2 (2003) /	
	63.	Kipnes et al. "The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 2001) (Poster) /	
	64.	Kipnes et al. "The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes" American Diabetes Association Annual Meeting (June 24, 2001) (Abstract) /	
	65.	Kube, D.M. "Multitalented Proteins Play a Key Role in Therapeutics" <i>Genomics and Proteomics</i> (Sept. 2002) /	
	66.	Maislos et al. "The Source of the Circulating Aggregate of Insulin in Type I Diabetic Patients is Therapeutic Insulin" <i>J. Clin. Invest.</i> 77:717-723 (1986) /	
	67.	Savva & Huang "Effect of PEG Homopolymer and Grafted Amphiphilic PEG-Palmitoyl on the Thermotropic Phase Behavior of 1,2-Dipalmitoyl-SN-Glycero-3-Phosphocholine Bilayer" <i>Journal of Liposome Research</i> 9(3):357-365 (1999) /	
	68.	Marschutz et al. "Oral Peptide Drug Delivery: Polymer-Inhibitor Conjugates Protecting Insulin from Enzymatic Degradation In Vitro" <i>Biomaterials</i> 21:1499-1507 (2000) /	
	69.	Musabayane et al. "Orally Administered, Insulin-Loaded Amidated Pectin Hydrogel Beads Sustain Plasma Concentrations of Insulin in Streptozotocin-Diabetic Rats" <i>Journal of Endocrinology</i> 164:1-6 (2000) /	
	70.	Nucci et al. "The Therapeutic Value of Poly(ethylene Glycol)-Modified Proteins" <i>Ad. Drug. Del. Rev.</i> 6:133-151 (1991) /	
	71.	Oka et al. "Enhanced Intestinal Absorption of a Hydrophobic Polymer-Conjugated Protein Drug, Smancs, in an Oily Formulation" <i>Pharm. Res.</i> 7(8):852-855 (1990) /	
	72.	Pang, David C. "Bridging Gaps in Drug Discovery and Development" <i>Pharmaceutical Technology</i> 22:82-94 (Nov. 1998) /	
	73.	Patel et al. "Oral Administration of Insulin By Encapsulation Within Liposomes" <i>FEBS Lett.</i> 62(1):60-63 (1976) /	
	74.	Price, JC <i>Polyethylene Glycol</i> , pp. 355-361 (<i>not dated</i>)	
	75.	Puskas et al. "Investigation of Chymotrypsin Digestion Profile of Orally Active Insulin Conjugate HIM2" <i>AAPS Pharm Sci.</i> 3(3) 2001 (Abstract) /	
	76.	Radhakrishnan et al. "Chemical Modification of Insulin with Amphiphilic Polymers Improves Intestinal Delivery," <i>Proceed. Intl. Symp. Control. Rel. Bioact. Mater.</i> 25:124-125 (1998) (Abstract) /	
	77.	Radhakrishnan et al. "Oral Delivery of Insulin: Single Selective Modification at B29-LYS With Amphiphilic Oligomer" Program and Abstracts, 1999 National Meeting of the Ameri. Assoc. Pharm. Scient., New Orleans, LA (1999) (Abstract)	

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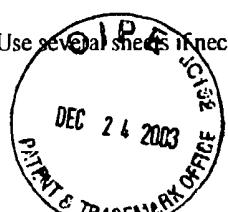
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80.	Ratner, R. E. et al. "Persistent Cutaneous Insulin Allergy Resulting from High-Molecular Weight Insulin Aggregates" <i>Diabetes</i> 39:728-733 (1990)		
81.	Richards et al. "Self-Association Properties of Monomeric Insulin Analogs Under Formulation Conditions" <i>Pharmaceutical Research</i> 15(9):1434-1441 (1998)		
82.	Robbins et al. "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients" <i>Diabetes</i> 36:838-841 (1987)		
83.	Russell-Jones, G. J. "Vitamin B12 Drug Delivery" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:102-103 (1992)		
84.	Saffran et al. "A Model for the Study of the Oral Administration of Peptide Hormones" <i>Can J Biochem</i> 57:548-553 (1979)		
85.	Saffran, M. et al. "A New Approach to the Oral Administration of Insulin and Other Peptide Drugs" <i>Science</i> 233:1081-1084 (1986)		
86.	Santiago et al. "Oral Immunization of Rats with Influenza Virus M Protein (M1) Microspheres" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:116-117 (1992)		
87.	Shah and Shen "Transcellular Delivery of an Insulin-Transferrin Conjugate in Enterocyte-like Caco-2 Cells" <i>Journal of Pharmaceutical Sciences</i> 85(12):1306-1311 (1996)		
88.	Shichiri et al. "Enteral Absorption of Water-in-Oil-in-Water Insulin Emulsions in Rabbits" <i>Diabetologia</i> 10:317-321 (1974)		
89.	Soltero et al. <i>Insulin Polypeptide-Oligomer Conjugates, Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same</i> U.S. Serial No. 10/382,022, filed 03/05/2003		
90.	Soltero et al. <i>Pharmaceutical Compositions of Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,069, filed 03/05/2003		
91.	Soltero et al. <i>Pharmaceutical Compositions of Insulin Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,155, filed 03/05/2003		
92.	Still and McAllister "Effects of Orally Active Modified Insulin in Type 1 Diabetic Patients" <i>Clinical Pharmacol. Therap.</i> 69(2):P95 (Feb. 2001) (Abstract)		
93.	Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Slide Presentation Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001		
94.	Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001 (Handout)		
95.	Still et al. "Magnitude and Variability of Pharmacokinetic and Glucodynamic Responses to Modified Human Insulin Administered Orally to Healthy Volunteers" <i>Diabetes Research and Clinical Practice</i> 56:S77 (2002)		
96.	Still et al. <i>Methods of Reducing Hypoglycemic Episodes in the Treatment of Diabetes Mellitus</i> , U.S. Serial No. 10/461,199, filed 06/13/2003		

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office		Attorney Docket Number 9233-63	Serial No. 09/873,797
LIST OF DOCUMENTS CITED BY APPLICANT			
(Use several sheets if necessary)			
			
		Applicants: Ekwuribe et al.	
		Filing Date June 4, 2001	Group 1651
97.	Still, J. Gordon "Development of Oral Insulin: Progress and Current Status" <i>Diabetes/Metabolism Research and Reviews</i> 18(1):S29-S37 (2002)		
98.	Still, J. Gordon "Oral Insulin Development" Slide Presentation, VI International St. Barts Symposium Diabetes 2000: Therapy and Technology, London, England, May 12, 2000		
99.	Szleifer et al. "Spontaneous Liposome Formation Induced by Grafted Poly(Ethylene Oxide) Layers: Theoretical Prediction and Experimental Verification" <i>Proceedings of the National Academy of Sciences of the United States of America</i> 95(3):1032-1037 (1998)		
100.	Taniguchi et al. "Synthesis of Acetyl Lysozyme and Improvement of its Lymphatic Transport Following Small Intestinal Administration in Rats" <i>Proceed. Intern. Symp. Control. Rel. Bioactiv. Mater.</i> 19:104-105 (1992)		
101.	Uchio et al. "Site-Specific Insulin Conjugates with Enhanced Stability and Extended Action Profile" <i>Advanced Drug Delivery Reviews</i> 35:289-306 (1999)		
102.	Wahren et al. "Role of C-peptide in Human Physiology" <i>Am. J. Physiol. Endocrinol. Metab.</i> 278:E759-E768 (2000)		
103.	Zalipsky et al. "Attachment of Drugs to Polyethylene Glycols" <i>Eur. Polym. J.</i> 19(12):1177-1183 (1983)		
104.	Ziv and Bendayan "Intestinal Absorption of Peptides Through the Enterocytes" <i>Microscopy Research and Technique</i> 49:346-352 (2000)		

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